Notice of Allowability	Application No.	Applicant(s)	
	10/051,770	GLICK ET AL.	
	Examiner	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment filed 1/15/2004 and Telephonic Interview on 3/20/04, 3/30/04 and 4/1/04*.

2. ☒ The allowed claim(s) is/are *51-106*.

3. ☒ The drawings filed on *1/18/2002* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

06/06/2004 FPATTERS 00000002 500772 10051770

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Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *4/1/04* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Peter Rogalskyj on March 30, 2004.

We propose canceling claims 1-50 and adding new claims 51-106. After amendment, 56 claims will be pending, of which 4 (i.e., claims 51, 65, 79, and 106) are independent. Applicants have previously paid for 50 total claims and 5 independent claims. Applicant is a small entity. Therefore, it is believed that applicant may need to pay an additional claims fee of $54.00 (i.e., 6 new claims in excess of those already paid for time $9.00 for each such claim). Please charge the fee to our deposit account no. 50-0772.

The application has been amended as follows:

Claims 1-50 (canceled).

Claim 51 (new): A composition comprising a first $\alpha_3\beta_4$ nicotinic receptor antagonist and a second $\alpha_3\beta_4$ nicotinic receptor antagonist, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist is 18-methoxycoronaridine or a pharmaceutically acceptable salt or solvate thereof and said second $\alpha_3\beta_4$ nicotinic receptor antagonist is mecamylamine or a pharmaceutically acceptable salt or solvate thereof.

Claim 52 (new): A composition according to claim 51, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist and said second $\alpha_3\beta_4$ nicotinic receptor antagonist are present in a weight ratio of from about 10:1 to about 1:10.

Claim 53 (new): A composition according to claim 51, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist and said second $\alpha_3\beta_4$ nicotinic receptor antagonist are present in a weight ratio of from about 5:1 to about 1:5.

Claim 54 (new): A composition according to claim 51, wherein said composition is in the form of a tablet, capsule, granular dispersible powder, suspension, syrup, or elixir.

Claim 55 (new): A composition according to claim 51, wherein said composition is in the form of a tablet or capsule and wherein said composition further comprises an inert diluent, a granulating agent, a disintegrating agent, a lubricating agent, or combinations thereof.

Claim 56 (new): A method for treating nicotine addiction in a patient, said method comprising: administering to the patient a composition according to claim 51.

Claim 57 (new): A method according to claim 56, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 58 (new): A method according to claim 56, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Claim 59 (new): A method for treating amphetamine addiction in a patient, said method comprising: administering to the patient a composition according to claim 51.

Claim 60 (new): A method according to claim 59, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 61 (new): A method according to claim 59, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Claim 62 (new): A method for treating opioid addiction in a patient, said method comprising: administering to the patient a composition according to claim 51.

Claim 63 (new): A method according to claim 62, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 64 (new): A method according to claim 62, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Claim 65 (new): A composition comprising a first $\alpha_3\beta_4$ nicotinic receptor antagonist and a second $\alpha_3\beta_4$ nicotinic receptor antagonist, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist is 18-methoxycoronaridine or a pharmaceutically acceptable salt or solvate thereof and said second

$\alpha_3\beta_4$ nicotinic receptor antagonist is dextromethorphan or a pharmaceutically acceptable salt or solvate thereof.

Claim 66 (new): A composition according to claim 65, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist and said second $\alpha_3\beta_4$ nicotinic receptor antagonist are present in a weight ratio of from about 10:1 to about 1:10.

Claim 67 (new): A composition according to claim 65, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist and said second $\alpha_3\beta_4$ nicotinic receptor antagonist are present in a weight ratio of from about 5:1 to about 1:5.

Claim 68 (new): A composition according to claim 65, wherein said composition is in the form of a tablet, capsule, granular dispersible powder, suspension, syrup, or elixir.

Claim 69 (new): A composition according to claim 65, wherein said composition is in the form of a tablet or capsule and wherein said composition further comprises an inert diluent, a granulating agent, a disintegrating agent, a lubricating agent, or combinations thereof.

Claim 70 (new): A method for treating nicotine addiction in a patient, said method comprising: administering to the patient a composition according to claim 65.

Claim 71 (new): A method according to claim 70, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 72 (new): A method according to claim 70, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Claim 73 (new): A method for treating amphetamine addiction in a patient, said method comprising: administering to the patient a composition according to claim 65.

Claim 74 (new): A method according to claim 73, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 75 (new): A method according to claim 73, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Claim 76 (new): A method for treating opioid addiction in a patient, said method comprising: administering to the patient a composition according to claim 65.

Claim 77 (new): A method according to claim 76, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 78 (new): A method according to claim 76, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Claim 79 (new): A composition comprising a first $\alpha_3\beta_4$ nicotinic receptor antagonist and a second $\alpha_3\beta_4$ nicotinic receptor antagonist, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist is

18-methoxycoronaridine or a pharmaceutically acceptable salt or solvate thereof and said second $\alpha_3\beta_4$ nicotinic receptor antagonist is bupropion or a pharmaceutically acceptable salt or solvate thereof.

Claim 80 (new): A composition according to claim 79, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist and said second $\alpha_3\beta_4$ nicotinic receptor antagonist are present in a weight ratio of from about 10:1 to about 1:10.

Claim 81 (new): A composition according to claim 79, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist and said second $\alpha_3\beta_4$ nicotinic receptor antagonist are present in a weight ratio of from about 5:1 to about 1:5.

Claim 82 (new): A composition according to claim 79, wherein said composition is in the form of a tablet, capsule, granular dispersible powder, suspension, syrup, or elixir.

Claim 83 (new): A composition according to claim 79, wherein said composition is in the form of a tablet or capsule and wherein said composition further comprises an inert diluent, a granulating agent, a disintegrating agent, a lubricating agent, or combinations thereof.

Claim 84 (new): A method for treating nicotine addiction in a patient, said method comprising: administering to the patient a composition according to claim 79.

Claim 85 (new): A method according to claim 84, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 86 (new): A method according to claim 84, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body

weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Claim 87 (new): A method for treating amphetamine addiction in a patient, said method comprising: administering to the patient a composition according to claim 79.

Claim 88 (new): A method according to claim 87, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 89 (new): A method according to claim 87, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Claim 90 (new): A method for treating opioid addiction in a patient, said method comprising: administering to the patient a composition according to claim 79.

Claim 91 (new): A method according to claim 90, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 92 (new): A method according to claim 90, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Claim 93 (new): A composition comprising a first $\alpha_3\beta_4$ nicotinic receptor antagonist and a second $\alpha_3\beta_4$ nicotinic receptor antagonist, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist is mecamylamine or a pharmaceutically acceptable salt or solvate thereof and said second $\alpha_3\beta_4$ nicotinic receptor antagonist is dextromethorphan or a pharmaceutically acceptable salt or solvate thereof.

Claim 94 (new): A composition according to claim 93, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist and said second $\alpha_3\beta_4$ nicotinic receptor antagonist are present in a weight ratio of from about 10:1 to about 1:10.

Claim 95 (new): A composition according to claim 93, wherein said first $\alpha_3\beta_4$ nicotinic receptor antagonist and said second $\alpha_3\beta_4$ nicotinic receptor antagonist are present in a weight ratio of from about 5:1 to about 1:5.

Claim 96 (new): A composition according to claim 93, wherein said composition is in the form of a tablet, capsule, granular dispersible powder, suspension, syrup, or elixir.

Claim 97 (new): A composition according to claim 93, wherein said composition is in the form of a tablet or capsule and wherein said composition further comprises an inert diluent, a granulating agent, a disintegrating agent, a lubricating agent, or combinations thereof.

Claim 98 (new): A method for treating nicotine addiction in a patient, said method comprising: administering to the patient a composition according to claim 93.

Claim 99 (new): A method according to claim 98, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 100 (new): A method according to claim 98, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Claim 101 (new): A method for treating amphetamine addiction in a patient, said method comprising: administering to the patient a composition according to claim 93.

Claim 102 (new): A method according to claim 101, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 103 (new): A method according to claim 101, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Claim 104 (new): A method for treating opioid addiction in a patient, said method comprising: administering to the patient a composition according to claim 93.

Claim 105 (new): A method according to claim 104, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.01 to about 10 mg/kg of the patient's body weight per day.

Claim 106 (new): A method according to claim 104, wherein the first $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body

weight per day and wherein the second $\alpha_3\beta_4$ nicotinic receptor antagonist is administered in an amount of from about 0.1 to about 5 mg/kg of the patient's body weight per day.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The primary reason for allowance of the claims is the applicant's showing of unexpected results of Figures 5 and 11.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571) 273-0584. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Patent Examiner
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Marianne Seidel
Examiner's Supervisor
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